



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,281	04/30/2001	Beverly Lynn Mangold	38602.0003	1022

25227 7590 04/14/2004
MORRISON & FOERSTER LLP
1650 TYSONS BOULEVARD
SUITE 300
MCLEAN, VA 22102

EXAMINER

GRASER, JENNIFER E

ART UNIT PAPER NUMBER

1645

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,281

Applicant(s)

ROTHROCK ET AL.

Examiner

Jennifer E. Graser

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-15 and 21-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-20 and 44-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Acknowledgment and entry of the Amendment submitted 12/24/03 is made.

Claims 1-49 are currently pending. Claims 1-15 and 21-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Claims 16-20 and 44-49 are currently under examination.

Claim Rejections - 35 USC § 112

1. Claims 16-20 and 44-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-20 and 44-49 are vague and indefinite because they fails to clarify that the antibody is "isolated" and/or "purified". The current antibodies read on antibodies which are present in the blood/serum of animals which have been exposed to *B.anthraxis* or *B.thuringiensis*. The term "diagnostic kit" is an intended use only. The only component required in claims 16 and 44-46 are antibodies, whether they are isolated or non-isolated. It is also unclear how unpurified or unisolated antibodies would be effective in a detection assay. Correction is required.

Claims 16-20 and 44-49 are vague and indefinite because it is unclear what it meant by the phrase "specifically reactive". How is the antibody reactive? The claim language should be changed to "specifically binds" in order to convey the type of reaction which is occurring. Correction is required.

Art Unit: 1645

Claims 16-20 and 44-49 are vague and indefinite because the description of the invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence or molecular weight of the protein to which the claimed antibody specifically binds, which would allow for one to identify the antibody without ambiguity. The broad mention that the antibody reacts against spores of vegetative cells of *B.anthraxis* (or *B.thuringiensis*) does not adequately define the claimed antibody. The spores and vegetative cells of *Bacillus* contain numerous surface antigens. It is unclear what the structural properties of the claimed antibody is since there is no recitation of its own properties, much less the structure or physical characteristics to which it binds. The claims should be amended to include specific structural characteristics in order to adequately describe and set forth the inventive concept, i.e., an isolated antibody which specifically binds to an epitope of the protein set forth in SEQ ID NO:1. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. Correction is required.

Claims 20 and 45-49 are vague and confusing because they fail to claim what Applicant regards as the invention. A review of the specification teaches that the inventive concept is antibodies which specifically bind to *B.anthraxis* and do not cross-react with other species of *Bacillus*. More particularly, it appears that isolated

Art Unit: 1645

antibodies which bind to the EA1 antigen appear to be the invention. However, claim 16 is drawn to antibodies which bind to *B.thuingiensis* and do not bind to *B.anthraxis*. See rejections under 112, first enablement and written description below.

Claim Rejections - 35 USC § 112-Scope of Enablement

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 16-20 and 44-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 'a diagnostic kit comprising an isolated antibody which specifically binds to an epitope of the EA1 polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:1", does not reasonably provide enablement for diagnostic kits comprising **any** antibodies which specifically react with vegetative cells or spores of *B.anthraxis* or *B.thuringiensis*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working

Art Unit: 1645

examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The instant claims are broadly drawn to diagnostic kits comprising **any** antibodies which specifically react against spores or vegetative cells of *B.thuringiensis*, but not *B.anthraxis* and/or *B.cereus*; and **any** antibodies which specifically react against spores or vegetative cells of *B.anthraxis*, but now *B.thuringiensis*. However, the instant specification is only enabled for antibodies which specifically bind to the EA1 protein set forth in SEQ ID NO:1. The specification does not teach any other antibodies, but merely recites prophetic methods for developing antibodies specific to *Bacillus* species. Antibodies to species of *Bacillus* other than *B.anthraxis* are described briefly on pages 6-7, yet no disclosure beyond the mere mention of the possibility of making such antibodies is provided. It would take undue experimentation for one of skill in the art to identify a completely new unique antibody which displays no cross-reactivity to other members of its Genus. The specification has only enabled antibodies unique to the EA1 polypeptide of *B.anthraxis*. There is a great deal of unpredictability in finding antibodies which can distinguish between the different species of *Bacillus*. There is very little guidance provided in the specification for finding an antibody unique to *B.thuringiensis* with no cross-reactivity to other species of *Bacillus*. There are no working examples provided with respect to other antibodies. While the skill of those in the art is high, the quantity of experimentation would be undue given the limited guidance provided by the specification. *Genentech Inc. v. Novo Nordisk A/S* (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling

Art Unit: 1645

disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." That requirement has not been met in this specification with respect to antibodies other than those which specifically bind an epitope of the EA1 protein set forth in SEQ ID NO:1.

Claim Rejections - 35 USC § 112-Written Description

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 16-20 and 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are broadly drawn to diagnostic kits comprising **any** antibodies which specifically react against spores or vegetative cells of *B.thuringiensis*, but not

Art Unit: 1645

B.anthraxis and/or *B.cereus*; and **any** antibodies which specifically react against spores or vegetative cells of *B.anthraxis*, but now *B.thuringiensis*. However, the instant specification is only enabled for antibodies which specifically bind to the EA1 protein set forth in SEQ ID NO:1. The specification does not teach any other antibodies, but merely recites prophetic methods for developing antibodies specific to *Bacillus* species. Antibodies to species of *Bacillus* other than *B.anthraxis* are described briefly on pages 6-7, yet no disclosure beyond the mere mention of the possibility of making such antibodies is provided. It would take undue experimentation for one of skill in the art to identify a completely new unique antibody which displays no cross-reactivity to other members of its Genus.

. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention."

With the exception of an isolated antibody which specifically binds to an epitope of the protein consisting of the amino acid sequence set forth in SEQ ID NO:1, the

Art Unit: 1645

skilled artisan cannot envision the detailed structure of the encompassed antibodies. Therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of making or isolating it. The antibody itself is required. A generic statement which defines a genus of antibodies only by their functional activity does not provide an adequate written description of the genus. While Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules, usually defined by an amino acid/nucleotide sequence, falling within the scope of the claimed genus. An adequate written description of the claimed antibodies requires a precise definition, such as by structure, formula, chemical name, and/or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

Claim Rejections - 35 USC § 102/103

6. Claims 16-19 and 44 are rejected under 35 U.S.C. 102(a) as anticipated by Long et al (J.Applied Microbio., August 1999. 87:214) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Long et al (J.Applied Microbio., August 1999. 87:214).

Long et al teach an antibody-based system for the detection of *Bacillus anthracis* in environmental samples. The reference teaches that they have developed antigen capture dipstick assays that can detect antibodies to *B.anthraxis* protective antigen and also dipsticks which can detect antibodies for *B.anthraxis* spores. It is taught that colloidal gold is used to visualize the reaction. This is colloidal particle based lateral

Art Unit: 1645

flow detection system. Although the reference does not specifically recite that the assay is not reactive against spores of *B.thuringiensis*, it does recite that the assay is specific for the detection and identification of *B.anthraxis*. The kit of claims 16-19 and 44 only requires antibody and a colloidal particle based lateral flow detection system and is therefore clearly anticipated by Long et al. The assembly of the reagents to these assays in a diagnostic kit would have been obvious to one of ordinary skill in the art at the time the invention was made for convenience and storage capabilities. Although the reference does not specifically recite that the antibody to *B.anthraxis* does not react with *B.thuringiensis*, it inherently would not since protective antigen is specific to *B.anthraxis* and the protective antigen of *B.anthraxis* is not found in *B.thuringiensis*. Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&).

7. Claim 16 and 44 is rejected under 35 U.S.C. 102(b) as being anticipated by Mesnage et al (Molec. Microbiol. 1997, 23(6): 1147-1155) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mesnage et al (Molec. Microbiol. 1997, 23(6): 1147-1155).

Mesnage et al teach antibodies to the *Bacillus anthracis* S-layer component, EA1. Antibodies to the surface array protein (Sap) are also taught. The diagnostic kits of claims 16 and 44 only require antibody to a spore or vegetative cell of *Bacillus*

Art Unit: 1645

anthracis, and not *B.thuringiensis* and is therefore anticipated by the reference. The major cell antigen to which the isolated antibodies bind in the Mesnage reference is 100% identical to the EA1 protein disclosed by Applicants. Applicants have disclosed in the instant specification that antibodies directed against this EA1 protein are antibodies which bind to *B.anthraxis*, but do not bind to *B.thuringiensis*. These antibodies are disclosed as the preferred embodiment in the instant specification. Although the reference does not specifically recite that the antibody to *B.anthraxis* does not specifically react with *B.thuringiensis*, it inherently would not since the antigen to which it binds is specific to *B.anthraxis* and the instant specification supports this finding. The antibodies to the EA1 protein would be identical to Applicant's antibodies to the EA1 antigen, i.e., the antibodies are raised against the same antigen. Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 1988). The assembly of the reagents to these assays in a diagnostic kit would have been obvious to one of ordinary skill in the art at the time the invention was made for convenience and storage capabilities. However, since the instant claims do not require any components other than the antibodies, the reference anticipates the claims.

8. Claim 16 and 44 is rejected under 35 U.S.C. 102(b) as being anticipated by Phillips et al (FEMS Microbio. Immunol. 1988. 47: 169-178) or, in the alternative, under

Art Unit: 1645

35 U.S.C. 103(a) as obvious over Phillips et al (FEMS Microbio. Immunol. 1988. 47: 169-178).

Phillips et al teach monoclonal antibodies against spore antigens of *Bacillus anthracis*. The kit of claims 16 and 44 only require antibody to a spore or vegetative cell and is therefore anticipated by the reference. Although the reference does not specifically recite that the antibody to *B.anthraxis* does not specifically react with *B.thuringiensis*, it inherently would not since the antigen to which it binds is specific to *B.anthraxis*. Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&). The assembly of the reagents to these assays in a diagnostic kit would have been obvious to one of ordinary skill in the art at the time the invention was made for convenience and storage capabilities. However, since the instant claims do not require any components other than the antibodies, the reference anticipates the claims.

9. Claims 16, 19 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al (WO 86/02363) or, in the alternative, under 35 U.S.C. 103(a) as obvious ov.

Wright et al teach monoclonal antibodies against antigens of *Bacillus*, including *B.cereus* and *B.anthraxis*. Kits comprising the antibodies are specifically taught. See page 13 and claim 38. The kit of claim 16 only requires antibody to a spore or

Art Unit: 1645

vegetative cell of any one of *Bacillus anthracis*, *B.thuringiensis* or *B.cereus* and is therefore anticipated by the reference. Although the reference does not specifically recite that the antibody to *B.anthraxis* does not specifically react with *B.thuringiensis* and vice versa, they inherently would not since the antigen to which the antibodies bind are specific to the particular species of *Bacillus*. Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&).

Claim Rejections - 35 USC § 103

10. Claims 16-20 and 44-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney et al (WO 99/55842) in view of Loomis et al (WO 99/64863).

Kearney et al teach monoclonal antibodies which are specifically reactive to spores from different species of *Bacillus*. It is taught that the antibodies are highly specific and can discriminate between spores of potentially lethal organisms, such as *B.anthraxis*, and other harmless closely related bacilli. See abstract. Figure 6 shows that *anti-Bacillus anthracis* antibody specifically bind *B.anthraxis* spores. Example 13, page 18, teaches a monoclonal antibody which specifically reacts with *B.anthraxis*, but is not at all reactive with *B.subtilis* or *B.thuringiensis*. Example 14, page 19, teaches a monoclonal antibody which specifically reacts with *B.thuringiensis*, but not *B.subtilis* or *B.anthraxis*.

However, Kearney et al does not particularly exemplify the use of a colloidal particle based lateral flow detection system.

Loomis et al teach that colloidal gold particle immunoassays have been successfully used in the prior art for many years. See pages 1-3. Loomis et al teach a more sensitive immunoassay test to what was known in the art. It is a colloidal colorimetric flow through and lateral flow assay. The entire test is conducted on a test strip and the detection antibody is preferably a Fab fragment that has been labeled with a 50-100nm gold particle and immobilized on a test pad. See page 4. It is taught that the use of capture dendrimers to align and secure capture antibodies on a solid surface insure that no immunological activity of the capture antibody is sterically hindered.

It would have been prima facie obvious to one of ordinary skill in the art to use the monoclonal antibodies taught by Kearney in a colloidal lateral flow detection system taught by Loomis et al because Loomis et al teaches that it is a highly sensitive detection assay which is simple, sensitive and specific. The test strips would provide a much more efficient and easy assay than the ELISAs described in Kearney et al. The colloidal lateral flow detection system would have been an obvious modification as it was known in the art as a simple detection system.

Response to Applicants' arguments:

Applicants have argued that Kearney's statement that their resulting antibodies are not all reactive with *B.subtilis* or *B.thuringiensis* is not accurate. This has been fully and carefully considered but is not deemed persuasive. Kearney states that as seen in

Art Unit: 1645

Example 6, a representative profile of more than 36 anti-anthrax antibodies which stain all spores but were not at all reactive with *B. subtilis* and *B. thuringiensis* spores. A similar strategy was used to isolate and characterize 10-100 antibody-forming hybridomas which reacted with *B. thuringiensis*. Again the pattern was similar with all reacting with *B. thuringiensis* but not *B. subtilis* or *B. anthracis*. These antibodies were cloned and are sequenced. The discriminatory ability of the antibodies is shown in Figures 8 and 9 where it is possible to clearly discriminate three distinct spore-staining by fluorescence in a mixture of the three kinds of spores *in vitro* and *in vivo*.

11. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mesnage et al (Molec. Microbiol. 1997, 23(6): 1147-1155) in view of Loomis et al (WO 99/64863).

Mesnage et al teach antibodies to the *Bacillus anthracis* S-layer component, EA1. It is disclosed that EA1 constitutes the main lattice of the *B. anthracis* S-layer, and is the major cell-associated antigen. See abstract. Antibodies to the surface array protein (Sap) are also taught. It is taught that a Western blot assay suggested that the antibodies were highly specific to *B. anthracis* and did not cross-react. See page 1150-1151. Electron microscopy using grids with rabbit anti-EA1 antibodies or rabbit anti-Sap antibodies, or on anti-Sap antibodies. The grids were incubated on colloidal gold anti-rabbit or anti-mouse coupled antibodies. The major cell antigen to which the isolated antibodies bind in the Mesnage reference is 100% identical to the EA1 protein disclosed by Applicants. Applicants have disclosed in the instant specification that antibodies directed against this EA1 protein are antibodies which bind to *B. anthracis*, but do not

Art Unit: 1645

bind to *B.thuringiensis*. These antibodies are disclosed as the preferred embodiment in the instant specification. However, Mesnage et al does not particularly exemplify the use of these antibodies in a colloidal particle based lateral flow detection system.

Loomis et al teach that colloidal gold particle immunoassays have been successfully used in the prior art for many years. See pages 1-3. Loomis et al teach a more sensitive immunoassay test to what was known in the art. It is a colloidal colorimetric flow through and lateral flow assay. The entire test is conducted on a test strip and the detection antibody is preferably a FAB fragment that has been labeled with a 50-100nm gold particle and immobilized on a test pad. See page 4. It is taught that the use of capture dendrimers to align and secure capture antibodies on a solid surface insure that no immunological activity of the capture antibody is sterically hindered.

It would have been prima facie obvious to one of ordinary skill in the art to use the antibodies taught by Mesnage et al in a colloidal lateral flow detection system as taught by Loomis et al to detect *B.anthraxis* because Mesnage et al teach that the antibodies are highly specific to *B.anthraxis* and that EA1 constitutes the main lattice of the *B.anthraxis* S-layer, and is the major cell-associated antigen. One of ordinary skill in the art would have a reasonable expectation that a specific antibody developed against the major cell-associated antigen of a bacterium to be very effective in detecting the bacterium in a sample. Loomis et al teaches that it is a highly sensitive detection assay which is simple, sensitive and specific. The use of the EA1 and/or Sap antibodies taught by Mesange in a colloidal lateral flow detection system would have been obvious

Art Unit: 1645

as a *B.anthraxis* detection system. The assembly of the reagents to these assays in a diagnostic kit would have been obvious to one of ordinary skill in the art at the time the invention was made for convenience and storage capabilities.

Response to Applicant's Arguments:

Applicants argue that Mesnage does not disclose or suggest a diagnostic kit that is specifically reactive against spores of *B.anthraxis* and not *B.thuringiensis*. This has been fully and carefully considered but is not deemed persuasive. As stated above, although Mesnage does not specifically recite that their antibodies do not react with *B.thuringiensis*, they inherently would not since the antigen to which the antibodies bind is specific to *B.anthraxis*, i.e., antibodies to the *Bacillus anthracis* S-layer component, EA1, or antibodies to the surface array protein (Sap). The antibodies to the EA1 protein would be identical to Applicant's antibodies to the EA1 antibody. Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&).

12. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

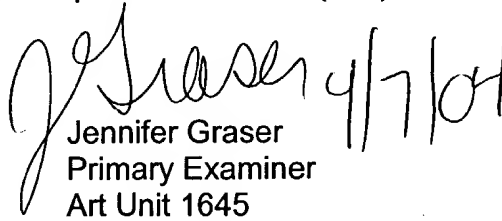
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571)

Art Unit: 1645

272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

 9/7/04
Jennifer Graser
Primary Examiner
Art Unit 1645